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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,969	12/17/2001	John M. Irving	084/002	6623

22869 7590 07/15/2003

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	9

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,969	Applicant(s) IRVING ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *5,6,8,12-15 and 18-25* is/are withdrawn from consideration.

5)☒ Claim(s) *4 and 17* is/are allowed.

6)☒ Claim(s) *1-3, 7, 9-11, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Amendment filed May 5, 2003 (Paper No. 8) in response to the Office Action of April 29, 2003 is acknowledged and has been entered. Claims 1-25 are pending and claims 1-4, 7, 9-11, 16 and 17 as they are drawn to YB-1 transactivator and TERT promoter (Election of Paper No. 6) are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The Office acknowledges the amendment to the specification removing the hyperlink from the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, **is withdrawn** in view of Applicant's amendment o the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 7, 9-11 under 35 U.S.C. 102(e) as being anticipated by Schiff (US 2002/0128221 A1) **is withdrawn** in view of applicant's amendment to the claims.

The rejection of claims 1, 2, 7, 9-11 under 35 U.S.C. 102(a) as being anticipated by Morin et al. (WO 00/46355, see IDS) **is withdrawn** in view of applicant's amendment to the claims.

The rejection of claims 1, 2, 7 and 11 under 35 U.S.C. 102(b) as being anticipated by Henderson et al. (U.S. Pat. No. 5,871,726) **is withdrawn** in view of applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7, 9-11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Schiff (US 2002/0128221 A1) and of Pham et al. (see IDS Paper NO. 4).

The instant invention is drawn to a replication-conditional (claim 17) or a replication competent adenovirus which has at least one transcriptional control element and an encoding region that replaces a function of E1a gene.

Schiff teaches the use of the hTERT promoter (paragraph 0062) for the control of the glycosyltransferase encoding region and the control of adenoviral genes required for replication (paragraph 0070, 0089 and 0090). The reference does not teach replacing the function of the E1a region with a heterologous sequence in order to retain a replication competent virus.

Pham et al. teaches that human cytomegalovirus IE1 and IE2 can functionally complement the adenovirus deleted E1A region and remain cytopathic ("the complete virus was efficiently packaged"). The reference teaches constructing a complete adenovirus containing the HCMV IE1 and HCMV IE2 gene using the ecdysone inducible E1 and E3 deletions.

It would have been obvious to one of ordinary skill in the art at the time the invention was filed to utilize a tissue specific promoter as taught by Schiff with the cytopathic virus taught by Pham et al. in order to create a tissue specific virus having cytopathic effect. One having ordinary skill in the art would have been motivated to do this in order to reduce recombination with wild type adenovirus.

Claims 1, 2, 7, 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Morin et al. (WO 00/46355, see IDS) and Pham et al. (see IDS Paper NO. 4).

The instant invention is drawn to a replication-conditional (claim 17) or a replication competent adenovirus which has at least one transcriptional control element and an encoding region that replaces a function of E1a gene.

Morin et al. discloses the use of the hTERT promoter in an oncloytic virus, a replication conditional adenovirus where the genetic element essential for replication is the adenovirus E1a region (see claims). The reference does not teach replacing the function of the E1a region with a heterologous sequence in order to retain a replication competent virus.

Pham et al. teaches that human cytomegalovirus IE1 and IE2 can functionally complement the adenovirus deleted E1A region and remain cytopathic ("the complete virus was

efficiently packaged"). The reference teaches constructing a complete adenovirus containing the HCMV IE1 and HCMV IE2 gene using the ecdysone inducible E1 and E3 deletions.

It would have been obvious to one of ordinary skill in the art at the time the invention was filed to utilize a tissue specific promoter as taught by Morin et al. with the cytopathic virus taught by Pham et al. in order to create a tissue specific virus having cytopathic effect. One having ordinary skill in the art would have been motivated to do this in order to reduce recombination with wild type adenovirus.

Claims 1, 2, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al. (U.S. Pat. No. 5,871,726) and Pham et al. (see IDS Paper NO. 4).

The instant invention is drawn to a replication-conditional (claim 17) or a replication competent adenovirus which has at least one transcriptional control element and an encoding region that replaces a function of E1a gene.

Henderson et al. disclose the use of a cytotoxic adenovirus where the adenovirus gene essential for propagation is under the transcriptional control of the prostate specific response element the adenovirus additional comprises a transgene that is under the control of the same prostate specific response element (see claims 1-4). The reference does not teach replacing the function of the E1a region with a heterologous sequence in order to retain a replication competent virus.

Pham et al. teaches that human cytomegalovirus IE1 and IE2 can functionally complement the adenovirus deleted E1A region and remain cytopathic ("the complete virus was

efficiently packaged"). The reference teaches constructing a complete adenovirus containing the HCMV IE1 and HCMV IE2 gene using the ecdysone inducible E1 and E3 deletions.

It would have been obvious to one of ordinary skill in the art at the time the invention was filed to utilize a tissue specific promoter as taught by Henderson et al. with the cytopathic virus taught by Pham et al. in order to create a tissue specific virus having cytopathic effect. One having ordinary skill in the art would have been motivated to do this in order to reduce recombination with wild type adenovirus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 7, 9-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7 and 11-14 of copending Application No. 09/994,427 in view of in view of Pham et al. (see IDS Paper NO. 4).

The instant invention is drawn to a replication-conditional (claim 17) or a replication competent adenovirus which has at least one transcriptional control element and an encoding region that replaces a function of E1a gene.

Schiff teaches the use of the hTERT promoter (paragraph 0062) for the control of the glycosyltransferase encoding region and the control of adenoviral genes required for replication (paragraph 0070, 0089 and 0090). The reference does not teach replacing the function of the E1a region with a heterologous sequence in order to retain a replication competent virus.

Pham et al. teaches that human cytomegalovirus IE1 and IE2 can functionally complement the adenovirus deleted E1A region and remain cytopathic ("the complete virus was efficiently packaged"). The reference teaches constructing a complete adenovirus containing the HCMV IE1 and HCMV IE2 gene using the ecdysone inducible E1 and E3 deletions.

It would have been obvious to one of ordinary skill in the art at the time the invention was filed to utilize a tissue specific promoter as taught by Schiff with the cytopathic virus taught by Pham et al. in order to create a tissue specific virus having cytopathic effect. One having ordinary skill in the art would have been motivated to do this in order to reduce recombination with wild type adenovirus.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

The objection of claims 4 to because of the following informalities **is maintained**. The claims are dependent on a rejected claim. Appropriate correction is required.

Conclusion

Claims 1,2, 7, 9-11 and 17 are rejected

Claim 4 is objected to.

Claim 17 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 7/14/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600